

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
GOLDENBERG  
Serial No.: 09/965,796  
Filed: October 1, 2001  
Title: IMMUNOTHERAPY OF B-CELL  
MALIGNANCIES USING ANTI-CD22  
ANTIBODIES  
Group Art Unit: 1643  
Examiner: Alana M. Harris  
Attorney Docket No.: IMMU:007US3

**EFS-WEB**

**DECLARATION UNDER 37 CFR § 1.132**

**MAIL STOP AMENDMENT**  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

Sir:

I, Myron Czuczman, being duly warned, declare as follows:

1. I am an Associate Professor of Medicine at the Roswell Park Cancer Institute, Buffalo, New York. I have an extensive background in the field of immunotherapy for cancer treatment, as evidenced by my Curriculum Vitae, which is attached. I have been a key investigator on clinical trials relating to immunotherapy of various B-cell malignancies, particularly rituximab. For example, I am currently a principal investigator for a Phase II trial studying the effects of giving rituximab together with liposomal doxorubicin to patients with relapsed or refractory B-cell non-Hodgkin's lymphoma and also for a Phase III Trial of CHOP plus rituximab versus CHOP plus iodine-131-labeled monoclonal anti-B1 antibody (tositumomab) for treatment of newly diagnosed follicular Non-Hodgkin's Lymphomas. I am also principal investigator for a phase II trial studying of the effects of administering rituximab together with galiximab to patients with stage II, stage III, or stage IV non-Hodgkin's lymphoma.

2. I am familiar with the article Maloney *et al.*, *Blood*, 84(8): 2457-2466 (1994). This article relates to results from a Phase I clinical trial to evaluate the safety of anti-CD20 antibody as a single agent therapeutic.

3. Maloney 1994 states, on page 2465, that "extension of these studies to patients with minimal disease, using antibody alone or in combination with conventional therapies, may provide the greatest benefit. The disclosure in Maloney that anti-CD20 may be combined with a "conventional therapy" would not have suggested to me therapy with a combination of an anti-CD20 antibody and another antibody, such as an anti-CD22 antibody. This is because "conventional therapies" at the time of the Maloney article, circa 1994, were chemotherapies, not antibody therapies. The current clinical trials which I referenced above in paragraph 1 both relate to combinations of the anti-CD20 antibody rituximab with a conventional drug therapy (liposomal doxorubicin or CHOP) along the lines envisioned by Maloney 1994.

4. "Conventional" means "conforming to established practice or accepted standards; traditional" (The American Heritage® Dictionary of the English Language: Fourth Edition - 2000). An investigational drug in Phase I clinical trials cannot be considered a conventional therapy, *i.e.*, it does not conform to established practice or accepted standards." By definition, investigational drugs have not been "accepted." Companies can provide investigational drugs to doctors if they are part of a drug trial covered by an FDA-approved protocol, and such drugs are by definition not conventional, since they are not available for use by any doctor on any patient.

5. In 1994 (and later) antibody therapies were not "conventional," and therefore Maloney's comment regarding the addition of "conventional therapies" to his anti-CD20 antibody suggests to a skilled clinician a combination of the anti-CD20 single antibody therapy with a chemotherapy. It would not have suggested therapy with a combination of antibodies. "Conventional therapies," circa 1994 and later, were chemotherapies. The first approved antibody for therapy of any malignancy was the anti-CD20 antibody rituximab that is the subject of Maloney, but it was not approved until 1997, and therefore there was no cancer therapy with any antibody that was a conventional therapy in 1994.

6. Treatment with anti-CD22 antibody was not conventional circa 1994. For example, Goldenberg *et al.*, *J. Clin. Oncol.*, 9: 548-564 (1991) relates to results from a pilot Phase I study involving a small number of patients to see the feasibility of giving this radiolabeled antibody, involving targeting tumor and organs, doses delivered to tumor and

normal organs, and any evidence of efficacy in a small number of patients, and does not establish that treatment with anti-CD22 antibody was "conventional." Juweid *et al. Cancer Res.*, 55:5899s-5907s (1995) is a follow-on report of further treatment of patients with low doses and initial results of high dose therapy in a Phase I trial. Here again, these were early investigational studies and do not represent conventional therapy.

7. Current reviews and texts support the fact that antibody therapy using a combination of antibodies to different targets is not conventional. No such combination therapy has been approved, and even combinations of rituximab with conventional chemotherapy for lymphoma have only been approved by the FDA within the past two years. Although some articles began to discuss the possibility of combination antibody therapies following publication by Immunomedics of their studies of epratuzumab and rituximab in about 2002/2003, none of these indicate that such therapy is "conventional." For example, "What is New in Lymphoma," published in 2004, cites rituximab as an advancement in the treatment of NHL. Cheson, *CA Cancer J Clin*, Sep-Oct; 54(5):260-72 (2004). Efforts to improve the activity of rituximab are noted, and include increasing the number of weekly infusions, delivering higher doses and increasing dose density. Combinations with CHOP are also mentioned. I published a report in 1999 showing that a combination treatment of anti-CD20 monoclonal antibody and CHOP chemotherapy (a "conventional therapy") showed improved efficacy. Czuczman *et al., Journal of Clinical Oncology*, 17:268, (1999). This is a treatment of anti-CD20 antibody and conventional therapy as mentioned in Maloney, but does not suggest combination antibody therapy. The Cheson article also references both a Phase II study of a combination of rituximab with epratuzumab and a phase I/II study of the combination of galiximab and rituximab, each of which were reported in 2003, demonstrating that combination antibody therapy was still very much investigational at this later date.

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I hereby declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

3/6/07  
Date

Myron Czuczman MD  
Myron Czuczman, MD

CURRICULUM VITAE  
MYRON S. CZUCZMAN, M.D.

March 20, 2007

Office Address: Roswell Park Cancer Institute Telephone: (716) 845-7695  
Elm & Carlton Streets Fax: (716) 845-1693  
Buffalo, NY 14263

Home Address: 14 Hummingbird Court Telephone: (716) 662-6142  
Orchard Park, New York 14127

Education: M.D., Pennsylvania State University College of Medicine, 1985  
B.S. Biochemistry and Certificate in Russian and East European Studies,  
Magna Cum Laude; University of Pittsburgh, 1981

Employment History:

Senior Member, Graduate Faculty of the University of Buffalo. 10/21/04-Present

Member, Tumor Immunology Program (emphasis on hematologic malignancies),  
7/02 – Present, Roswell Park Cancer Institute, Buffalo, New York

Associate Professor of Medicine, with full tenure, 4/01-present, Roswell Park  
Cancer Institute, Buffalo, New York

Assistant Professor of Medicine, 7/92-3/01, Roswell Park Cancer Institute,  
Buffalo, New York

Covering Physician, 7/90-6/92, Urgent Care Center, Memorial Sloan-Kettering  
Cancer Center.

Covering Physician, 9/90-6/91, Autologous Bone Marrow Transplant Unit,  
Memorial Sloan-Kettering Cancer Center.

Research Assistant, Summer of 1982 and 1983, Department of Biochemistry,  
Pennsylvania State University College of Medicine. Laboratory of Dr. Eugene  
A. Davidson, Ph.D.

Research Assistant, 1980-1981, Department of Biochemistry, University of  
Pittsburgh School of Medicine. Laboratory of Dr. Robert H. Glew, Ph.D.

HONORS, AWARDS:

Phi Beta Kappa, 1981

NIH Medical Scientist Training Grant, Summer of 1982 and 1983

Memorial Sloan-Kettering Clinical Scholar's Training Grant, July 1990-1992  
(\$8,550/year)

Selected to the 1999 Edition of "The Best Doctors in America", Woodward / White, Inc.

Department of Medicine "Best Teacher Award" 1999-2000 and 2003-2004:  
Selected by Hematology/Oncology Fellows

Elected to America's Registry of Outstanding Professionals, 2002-2003

Elected to Strathmore's Who's Who, 2002-2003

Selected to "America's Top Physicians, 2003"

Nominated as International Health Professional of the Year for 2004, from the International Biographical Centre, Cambridge, England

Selected to the 2001-2002, 2003-2004, 2004-2005 Editions of "The Best Doctors in America", Castle Connolly Medical, Ltd.

Nominated as Man of the Year, 2004, by the Governing Board of Editors of the American Biographical Institute

Chosen for a "Patient Service Award" by The Leukemia & Lymphoma Society (Western New York & Finger Lakes Chapter), December 2005

Selected to represent Buffalo, NY in the 2006 Edition of The Metropolitan Who's Who Professional Honor Society.

#### PROFESSIONAL CERTIFICATION:

Diplomate in Internal Medicine  
September, 1988

Board Certified in Medical Oncology (#120978)  
November, 1991

New York State Licensed Physician:  
169807-1

#### POSTDOCTORAL TRAINING:

Cornell's North Shore University Hospital/Memorial Sloan-Kettering Cancer Center Program, Internship and Residency, 1985-1988

Memorial Sloan-Kettering Cancer Center, Medical Oncology/Hematology Fellow, 1988 - 1992

Laboratory of Hematopoietic Cancer Immunochemistry, Sloan-Kettering  
Institute, Senior Research Fellow, 1989 - 1992

ACADEMIC APPOINTMENTS:

10/21/04-Present	Senior Member, Graduate Faculty of the University of Buffalo Roswell Park Cancer Institute State University of New York at Buffalo
4/02 – Present	Member, Tumor Immunology Program Roswell Park Cancer Institute State University of New York at Buffalo
4/01 - Present	Associate Professor of Medicine Division of Medicine Departments of Hematologic Oncology and Bone Marrow Transplantation Roswell Park Cancer Institute State University of New York at Buffalo
5/98 - Present	Head, Lymphoma/Myeloma Service Division of Medicine Departments of Hematologic Oncology and Bone Marrow Transplantation Roswell Park Cancer Institute State University of New York at Buffalo
4/97 - 2/98	Medicine Clinic Physician Coordinator Roswell Park Cancer Institute, Buffalo, NY Jerome W. Yates, M.D., M.P.H., Acting Chair, Division of Medicine
7/95 - Present	Medical Staff Buffalo General Hospital 100 High Street Buffalo, New York 14203
5/94 - Present	Adjunct Faculty Physician Assistant Program D'Youville College One D'Youville Square 320 Porter Avenue Buffalo, NY 14201-1084

7/1/92 – 3/01

Assistant Professor of Medicine  
Division of Medicine  
Departments of Hematologic Oncology and  
Bone Marrow Transplantation  
Roswell Park Cancer Institute  
State University of New York at Buffalo

#### PROFESSIONAL MEMBERSHIPS:

Member, American Association of Cancer Research  
Member, Cancer and Leukemia Group B  
Member, American Society of Hematology  
Member, American Society of Clinical Oncology  
Member, American Cancer Society  
Member, National Comprehensive Cancer Center

#### NATIONAL SERVICE:

Member, National Comprehensive Cancer Network (NCCN) Lymphoma  
Guidelines Panel, 6/97 - Present

Member (original), National Comprehensive Cancer Network (NCCN) NHL  
Outcomes Database Panel, 11/99 – Present

Study co-chair of Cancer and Leukemia Group B Protocol 8364 "Immunological  
Diagnostic Studies in Adult ALL"

Reviewer, American Society of Hematology, Category: Lymphoma Therapy,  
Excluding Transplantation. Abstracts for 12/99 Meeting

Chair, Session: "Antibody-based Therapy of B-Cell Lymphomas" American  
Society of Hematology, 12/99 Meeting

Cadre Member, Lymphoma Committee, Cancer and Leukemia Group B  
(CALGB) 1/00 - Present

National Chair, Cancer and Leukemia Group B (CALGB) Protocol 59901 "A  
phase II study of 506U78 in patients with previously systemically untreated  
cutaneous T-cell lymphoma (CTCL) or with refractory or relapsed non-  
cutaneous peripheral T-cell lymphoma (PTCL). 1/00 – 2004; Manuscript  
submitted for publication, 11/05

Study Chair of Cancer and Leukemia Group B Protocol 50102/SWOG S0016 "A  
Phase III Trial of CHOP vs. CHOP + Rituximab vs. CHOP + Iodine-131 Labeled  
Monoclonal Anti-B1 Antibody (Tositumomab) for Treatment of Newly  
Diagnosed Follicular Non-Hodgkin's Lymphoma" 12/15/01 - Present



Organizer and Annual Co-Chairman of the International Workshop on NHL (IWNHL), 1<sup>st</sup> held in November, 2002 (France); continues as an annual international event

Chair, Harvard Cancer Center's Drug and Safety Monitoring Committee for Waldenström's multicenter clinical trials. 1/01/02 – 12/31/03

Member, Editorial Board of the American Journal of Oncology Review (AJOR). 01/01/02 – Present

Member, Editorial Board for "NHL Updates". 07/01/02 – Present

Member, Editorial Board for "Targeted Therapies" ([www.tgt-therapies.com](http://www.tgt-therapies.com)). 01/01/04 – present.

Member, Editorial Board for "Current Hematologic Malignancy Reports. 11/05 – present

Moderator, ASH 2005: Lymphoma: Therapy with Biologic Agents, excluding pre-Clinical Models 1. (Co-Moderator: Bruce Peterson, MD, U of MN) December 12, 2005. Atlanta, GA.

Ad Hoc Member, NCI PO1 Review Study Group, Hematologic Malignancies Cluster Review, Subcommittee D, 2/06 - present

#### INSTITUTE / COMMUNITY SERVICE:

Member of Institutional Review Board, RPCI, 8/92 to 9/99; reappointed 10/05 - present

Elected Member of RPCI Medical Staff Executive Committee, 4/95  
Representative At Large - 2 years; Re-elected for additional 2 year term, 4/97

Member, Board of Directors, Western District American Cancer Society, New York State Division, 8/95 - 8/99

Member, Operating Room Committee, 6/96 - 7/98

Member, Task Force on Managed Care and Marketing at RPCI since 3/97

Member, Focus Group for Redeveloping the Referral Office at RPCI since 9/97

Member, Critical Care Committee since 6/96 - 8/04

Member, Search Committee for Chairman of Immunology Department, 1998

Elected to Board of Directors, Roswell Park Community Cancer Network IPA, Inc., 2/99 to present

Member, Primary Care Task Force, since 5/99

Elected Member of RPCI Medical Staff Executive Committee, 5/00  
Representative At Large - 2 years; Re-elected for additional 2 year term, 4/02

Member, Strategic Leadership Council, RPCI, 6/00

Member, Fellowship Research Review Committee, RPCI, 7/02 – present

Member, Conflict of Interest Task Force, RPCI, 12/02 – present

Member, Health Information/Medical Records Committee, RPCI, 9/04 - 07/05

Member, Clinical Leadership Committee, RPCI 11/00; reappointed 5/1/05 - present

#### JOURNAL REFEREE:

American Journal of Hematology  
American Journal of Oncology Review  
Annals of Hematology  
Blood  
British Journal of Haematology  
Cancer  
Cancer Investigation  
Clinical Cancer Research  
Clinical Lymphoma  
Journal of Clinical Oncology  
Oncology

#### EDITORIAL BOARD:

The American Journal of Oncology Review  
NHL Updates (Darwin Medical Communications)  
Current Hematologic Malignancy Reports

#### DEPARTMENTAL SERVICE:

Coordinator of Hematology/Oncology Module for Physician Assistant students at D'Youville College, 1994-2003.

## TEACHING AND PRECEPTORSHIP:

1992 - Present	Attending on inpatient Hematology Oncology/BMT Service with fellows and residents Roswell Park Cancer Institute
1992 - Present	Attending in Medical Oncology Clinic with fellows, medicine residents, and medical students Roswell Park Cancer Institute, 2 days/week
1994 – Present	Lecturer, first year medical student Cancer Selective State University of New York at Buffalo
1994 – 2003	Lecturer, Clinical Medicine II Physician Assistant Program D' Youville College, Buffalo, NY
1996 – Present	Lecturer, Fellows Oncology Syllabus Roswell Park Cancer Institute
1997 – Present	Lecturer, third year medical student Oncology Selective State University of New York at Buffalo
1997 – Present	Preceptor, Summer Medical Student Program Roswell Park Cancer Institute Varada Nargund, Lake Erie Osteopathic College (1997) William Lee, SUNY Health Science Center (1998) John Hayslip, North East Ohio (1998) Jeff Davis, University of North Dakota (1999) David Cipolla (2001) Gregory Connolly (2001) Scott Reising (2002) Adam Kotowski (2003) Adam Schweickert (2004)
1998	Thesis Advisor, Master's Degree State University of New York at Buffalo Roswell Park Cancer Institute Mark Chester "Comparative sensitivity of an RT-PCR versus PCR-Based assay for the detection of clonal IgH gene rearrangement"
2000	Preceptor, Senior Hematology / Oncology Research Fellow Project Francisco Hernandez, MD "Elucidation of mechanisms of action and resistance pathways of biologically active monoclonal antibodies" (in collaboration with Betsy Repasky, Ph.D., Dept of Immunology, RPCI)
2003 -	Sponsor and Mentor for Jeyanthi Ramanarayan

	<p>ASCO Young Investigator Award Recipient  The Laboratory of Translational Lymphoma Research  (Head, Myron S. Czuczman, MD)  Title of Research: "Targeting Bcl-2 expression in rituximab-resistant lymphoma cells as a therapeutic strategy to overcome monoclonal antibody acquired resistance"  Current Position: Assistant Professor of Hematology and Oncology, VA Medical Center, Albany, NY</p>
2003-2004	<p>PESP NY State Research Award  (Funding for Translational Cancer Research Training)  Recipient: Nishita Reddy, MD  Current Position: Chief Fellow, RPCI Hematology / Oncology Fellowship Program</p>
2004 – Present	<p>Co-Mentor and Advisor (along with Dr. James Clements, Department of Immunology) in the Laboratory of Translational Lymphoma Research (Head, Myron S. Czuczman, MD)  Ph.D. Candidate: Scott Olejniczak, MS  Title of Ph.D. Thesis: "Role of multi-domain Bcl-2 family proteins in shared resistance to rituximab and chemotherapy"</p>
2005-2007	<p>Re-awarded PESP NY State Research Award (2 year term)  Recipient: Raymond Cruz, MD</p>

#### RESEARCH ACTIVITIES:

Clinical research studying monoclonal antibodies either alone or in combination with other agents (i.e. primarily chemotherapy) in the treatment of lymphoid neoplasms.

Clinical research evaluating the significance of minimal residual disease in lymphoid malignancies.

Principal Investigator on several unlabeled and radiolabeled monoclonal antibody clinical trials for non-Hodgkin's lymphoma: Investigator-initiated, pharmaceutical-sponsored, and CALGB-sponsored trials.

Study of immunophenotype of lymphoid neoplasms by multiparameter flow cytometry.

#### GRANT SUPPORT, Completed:

Memorial Sloan-Kettering Clinical Scholar's Training Grant, July 1990-1992 (\$8,550/year)

ACS Grant # PRTF-135, P.I.: Myron S. Czuczman, July 1, 1990 - June 30, 1992, \$47,000

NIH CA59518 "Cancer and Leukemia Group B RPCI / SUNY AB" P.I. Ellis Levine, MD, Co-P.I. Myron S. Czuczman, MD. 4/93 – 3/31/98 \$767,333.00

NIH CA59518 "Cancer and Leukemia Group B RPCI / SUNY AB" P.I. Ellis Levine, MD, Co-P.I. Myron S. Czuczman, MD. 4/98 – 3/31/00 \$487,712.00

Burroughs Wellcome, Co. P.I. Myron S. Czuczman. A Pilot Study of CAMPATH-1H in Patients with Minimal Residual non-Hodgkin's Lymphoma Detectable by Polymerase Chain Reaction. \$56,000.00. (Completed.)

Burroughs Wellcome, Co. P.I. Myron S. Czuczman. A Multi-Center Phase II Study of CAMPATH-1H in Patients with non-Bulky non-Hodgkin's Lymphoma. \$11,000.00. (Completed.)

IDEC Pharmaceuticals, Corp., P.I. Myron S. Czuczman. Pilot Phase II Study to evaluate the safety and clinical activity of IDEC-C2B8 in combination with chemotherapy (CHOP) in patients with low grade B-cell lymphoma. Activated 4/1/94. \$94,500.00. (Completed.)

IDEC Pharmaceuticals, Corp., P.I. Myron S. Czuczman. Phase II multicenter study to evaluate the safety and efficacy of once weekly times 4 dosing of IDEC-C2B8 in patients with relapsed low grade or follicular B-cell lymphoma. Activated 5/1/96. \$44,000.00. (Completed.)

IDEC Pharmaceuticals, Corp., P.I. Myron S. Czuczman. Phase II multicenter study to evaluate the safety and efficacy of once weekly times 8 dosing of IDEC-C2B8 in patients with relapsed low grade or follicular B-cell lymphoma. Activated 5/23/96. \$18,000.00. (Completed.)

Genentech, Inc. P.I. Myron S. Czuczman. Phase II pilot study of safety and efficacy of IDEC-C2B8 in combination with CHOP chemotherapy in previously untreated patients with intermediate or high grade non-Hodgkin's lymphoma. Activated 10/23/96. \$26,000.00. (Completed.)

Immunomedics, Inc., P.I. Myron S. Czuczman. Phase I/II study of <sup>131</sup>I-LL2 murine IgG antibody in patients with non-Hodgkin's lymphoma. \$47,386.50. (Completed)

IDEC Pharmaceuticals, Corp., P.I. Myron S. Czuczman. A randomized phase III multi-center, controlled trial to evaluate the efficacy and safety of IDEC-Y2B8 Radioimmunotherapy Compared to Rituxan™ immunotherapy of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma. \$60,000.00 (Completed, 8/99)

NIH RO-1 CA 67026-04 grant, Co-P.I. Myron S. Czuczman, 8/99 – 7/02: Radioimmunotherapy of non-Hodgkin's lymphoma with LL2 monoclonal antibody. *Early studies of <sup>90</sup>Yttrium-labeled humanized LL2 (anti-CD22) monoclonal antibody.* Total: \$228,770.00 (3 year award to RPCI).

#### GRANT SUPPORT, Current:

**PO1 CA103985-1. National Health Institute. (PI, Project 3) 09/12/2005 to 09/12/2009**  
"Targeting therapy of B-cell lymphoma". This is a combined effort between three Cancer Institutes to develop new targeted therapies for B-cell malignancies by improving the anti-tumor activity of Monoclonal antibodies. The Participating Institutions are: The Garden State Cancer Center, Fox Chase Cancer Center and Roswell Park Cancer Institute. 10% effort on project.

**PESP-New York State program (PI). 07/01/05-7/01/07**

Targeting CD52 in rituximab resistant B-cell lymphomas. The major goal of this program is to study the effects of CD52 upregulation in rituximab resistance. In addition this program is intended to foster the development of the academic career of a physician on training to conduct translation research.

**BC020043 Department of Defense Breast Cancer Research Program (BCRP). P.I. Ben Seon, Ph.D., co-P.I. Myron S. Czuczman, MD, 4/1/04 – 3/31/08:**

Vascular Targeting Anti-Angiogenic Therapy of Human Breast Cancer. 5% effort on project. Total: \$3,251,260.00

**PESP-New York State program (PI). 07/01/03-7/01/04**

*Preclinical in vitro and in vivo characterization of the effects of immunomodulatory drugs (IMiDs) on the anti-tumor activity of biologically active monoclonal antibodies directed against Non-Hodgkin's Lymphoma (NHL).* The major goal of this program is to study the effects of CC5013 and CC4047 in the anti-tumor activity of rituximab and other monoclonal antibodies. In addition this program is intended to foster the development of the academic career of a physician on training to conduct translation research.

Kern McNeill International, P.I. Myron S. Czuczman (RPCI). The effects of PROCRT® (Epoetin alfa) on Hemoglobin, symptoms distress and quality of life during chemotherapy in lymphoma patients with mild to moderate anemia. \$68,000.00 to date. Accrual completed in 2004. Manuscript submitted for publication.

Genentech Inc. and Berlex Labs, P.I. Myron S. Czuczman. (Single institution study) Phase II pilot study of the safety and efficacy of Rituxan (Chimeric anti-CD20 antibody) in combination with Fludarabine chemotherapy in patients with low-grade or follicular lymphoma. \$100,000.00. Accrual completed 12/00. Manuscript published in J Clin Oncol, 2005.

IDEC Pharmaceuticals, Corp., P.I. Myron S. Czuczman. A Phase II open label multi-center trial to evaluate the efficacy and safety of IDEC-Y2B8 radioimmunotherapy in patients with B-cell non-Hodgkin's lymphoma who have not responded to prior Rituximab therapy. \$26,000.00 to date. Accrual completed. Manuscript published in J Clin Oncol, 2002.

Roswell Park Cancer Institute Alliance Foundation Award: Radioimmunotherapy of B-cell lymphoma with <sup>90</sup>Y-hLL2 radiolabeled monoclonal antibody. \$5,000.00 (for supplies).

IDEC Pharmaceuticals, Corp. P.I. Myron S. Czuczman. Expanded access study of IDEC-Y2B8 radioimmunotherapy of relapsed or refractory low-grade or follicular B-cell non-Hodgkin's lymphoma. \$50,000.00. Accrual completed.

Fannie Rippel Foundation, Co-P.I.'s Myron S. Czuczman, MD (Medicine) and Dominick Lamonica (Nuclear Medicine): Awarded \$200,000.00 grant for purchase of dual-head gamma camera imaging system to be utilized for radioimmunotherapy clinical studies at RPCI. January, 2001.

## PUBLICATIONS:

1. Glew RH, Diven WF, Zidian JL, Rankin BB, **Czuczman MS**, Axelrod AE. Metabolism of Lysosomal Enzymes in the Protein-Deficient Weanling Rat. *Am J Clin Nutr* 35(2):236-249. 1982.
2. Glew RH, **Czuczman MS**, Diven WF, Berens RL, Pope MT, Katsoulis DE. Partial Purification and Characterization of Particulate Acid Phosphatase of *Leishmania donovani* Promastigotes. *Comp Biochem Physiology (B)* 72:581-590. 1982.
3. Barsoum AL, **Czuczman MS**, Bhavanandan VP, Davidson EA. Epitopes Immunologically Related to Glycophorin A on Human Malignant and Non-malignant Cells in Culture. *Int J Cancer* 34:789-795. 1984.
4. **Czuczman MS**, Divgi CR, Straus DJ, Lovett D, Garin-Chesa P, Yeh S, Feirt N, Graham M, Leibel S, Gee TS, Myers J, Pentlow K, Finn R, Oettgen HF, Larson SM, Old LJ, Scheinberg DA. <sup>131</sup>Iodine-labeled Monoclonal Antibody Therapy of Acute Myelogenous Leukemia and B cell Lymphoma. *Antibody, Immunoconj and Radiopharm* 4(4):787-793. 1991.
5. **Czuczman MS** and Scheinberg DA. Monoclonal Antibody Therapy for NHL. *Contemporary Oncology* 2(7):45-52. 1992.
6. **Czuczman MS**, Garin-Chesa P, Lemoli RM, and Scheinberg DA. IgM Monoclonal Antibody JD118 Recognizes an Inducible Antigen Target for Human Complement Mediated Cytotoxicity Against Neoplastic B Cells. *Cancer Immunol and Immunother* 36:387-396. 1993.
7. **Czuczman MS**, Class K, Scheinberg DA. Interleukin-4 Priming Enhances a Target for Human Complement-Mediated Cytotoxicity of CLL. *Leukemia* 7(7):1020-1025. 1993.
8. **Czuczman MS**, Straus DJ, Divgi CR, Garin-Chesa P, Finn R, Myers J, Leibel S, Graham M, Larson S, Oettgen HF, Old LJ, and Scheinberg DA. A Phase I Dose Escalation Trial of <sup>131</sup>I-labeled Monoclonal Antibody OKB7 in Patients with non-Hodgkin's Lymphoma. *J Clin Oncol* 11(10):2021-2029. 1993.
9. Berinstein NL, Grillo-Lopez AJ, White CA, Bence-Bruckler I, Maloney D, **Czuczman M**, Green D, Shen D. Association of serum Rituximab (IDEC-C2B8) concentration and anti-tumor response in the treatment of recurrent low-grade or follicular non-Hodgkin's lymphoma. *Annals of Oncology* 9:995-1001, 1998.
10. McLaughlin P, Grillo-Lopez AJ, Link BK, Levy R, **Czuczman MS**, Cohen R, Heyman MR, Bence-Bruckler I, Jain V, Ho AD, Lister J, White CA, Cabanillas F, Wey K, Shen D, Dallaire B. Rituximab chimeric anti-CD20 monoclonal antibody therapy for relapsed indolent lymphoma: half of patients respond to a four-dose treatment program. *J Clin Oncol* 16:2825-2833, 1998.
11. Leget GA, **Czuczman MS**. Use of rituximab, the new FDA-approved antibody. *Current Opinion in Oncology* 10:548-551, 1998.

12. **Czuczman MS**, Grillo-Lopez AJ, White CA, Saleh M, Gordon L, LoBuglio AF, Jonas C, Klippenstein D, Dallaire B, and Varns C. Treatment of Patients with Low-Grade B-cell Lymphoma with the Combination of Chimeric Anti-CD20 Monoclonal Antibody and CHOP Chemotherapy. *J Clin Oncol* 17:268-276, 1999.
13. **Czuczman MS**. Combined modality therapy using CHOP plus Rituxan in patients with low grade lymphoma. *Biological Therapy of Lymphoma*. 2(1):2-6, 1999.
14. Alidina A, Lawrence D, Ford LA, Baer MR, Bambach B, Bernstein S, **Czuczman MS**, Slack J, Spangenthal E, Wetzler M, Barcos MP, Proulx G, Anderson B, McCarthy Jr. PL. Thiotepe-associated cardiomyopathy during blood or marrow transplantation association: Association with female gender and cardiac risk factors. *Biology of Blood and Marrow Transplantation*, 5:322-327, 1999.
15. **Czuczman MS**, Dodge RK, Stewart CC, Frankel SR, Davey FR, Powell BL, Szatrowski TP, Schiffer CA, Larson RA, Bloomfield CA. Value of Immunophenotype in Intensively Treated Adult Acute Lymphoblastic Leukemia: Cancer and Leukemia Group B Study 8364. *Blood* 93(11):3931-3939, 1999.
16. **Czuczman MS**, Adis New Drug Profile: Rituximab, A Viewpoint. *Drugs* 58(1):89, 1999.
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- grade, follicular or transformed B-cell NHL: Final results of a randomized controlled trial. Proc ASCO 22:2315, 2003.
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119. Chanan-Khan A, Miller K, Srinivasan S, McCarthy P, Alam A, Bernstein ZP, **Czuczman MS**. Combination of Melphalan (M), Ascorbic acid (A) and Trisenox (T) (MAT) as salvage therapy for patients (pts) with relapsed/refractory Multiple Myeloma (MM). *Blood* 102:11, 5284, 2003.
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124. Ramanarayanan J, Hernandez-Ilizaliturri FJ, **Czuczman MS**. Oblimersen sodium (G3139) targeting bcl-2 mRNA potentially overcomes acquired resistance to rituximab and sensitizes rituximab-resistant non-Hodgkin' s lymphoma (NHL) cells to rituximab-associated complement mediated cytotoxicity (CMC) and antibody dependent cellular cytotoxicity (ADCC). Proc ASCO 22:3180, 2004.
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126. Scarpace SL, Miller K, Elefante A, **Czuczman MS**, McCarthy P, Chanan-Khan A. Cost-utility of darbepoetin alfa (DARBE) on an every-2 week (QOW) schedule in anemic non-myeloid hematologic malignancies: A positive overall impact on the healthcare system (HCS). Proc ASCO 22:8278, 2004.
127. Reddy NM, Hernandez-Ilizaliturri FJ, **Czuczman MS**. The role of natural killer (NK) cell expansion and activation on the in vivo anti-tumor activity of Immunomodulatory drug (IMiD) CC4047) plus rituximab in a severe combined immunodeficiency (SCID) lymphoma mouse model. Proc ASCO 22:2556, 2004.
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129. Friedberg JW, Kho ME, Lepisto EM, Rodriguez MA, TerVeer A, LaCasce AS, Nademanee AP, Millenson M, **Czuczman M**, Niland J, Zelenetz AD, Weeks JC. Evolution of rituximab as "standard" therapy in patients (pts) with newly diagnosed follicular (fl), mantle cell (MCL), and diffuse large B-cell (DLCL) non-Hodgkin' s lymphoma (NHL) in 5 United States comprehensive cancer centers: An analysis from the National Comprehensive Cancer Network (NCCN) NHL Outcomes Project. Blood 104(11):1391, 2004.
130. **Czuczman MS**, Skipper M, Mohr A, Bernstein ZP, McCarthy P, Hernandez-Ilizaliturri F, Chanan-Khan AA.. Phase I/II study of Rituxan (R) in combination with Doxil (D) in patients (pts) with relapsing or refractory B-cell lymphoma: Promising early results. Blood 104(11): 1396, 2004.
131. Ramanarayanan J, Hernandez-Ilizaliturri FJ, **Czuczman MS**. In vivo downregulation of Bcl-2 by G3139 (G) enhances rituximab (R) anti-tumor activity: Effect of sequential versus concurrent G3139 administration on survival in a lymphoma-bearing SCID mouse model. Blood 104(11):1398, 2004.

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133. Hernandez-Ilizaliturri FJ, Gowda AC, Brombos D, Spear D, **Czuczman MS**. The effects of alemtuzumab (A) dose-sequence upon rituximab (R)-induced reorganization of lipid raft domains and in vitro/in vivo anti-tumor activity. *Blood* 104(11):2289, 2004.
134. Olejniczak SH, Hernandez FJ, **Czuczman MS**. Acquisition of rituximab resistance is associated with the development of chemotherapy resistance in B-cell lymphoma cells: Evidence of shared pathways of resistance between chemotherapeutic agents and biological therapies. *Blood* 104(11):2297, 2004.
135. Chanan-Khan AA, Miller KC, McCarthy P, DiMiceli LA, Yu J, Bernstein ZP, **Czuczman MS**. A Phase II study of velcade (V), Doxil (D) in combination with low-dose thalidomide (T) as salvage therapy for patients (pts) with relapsed (rel) or refractory (ref) multiple myeloma (MM) and Waldenstrom Macroglobulinemia (WM): Encouraging preliminary results. *Blood* 104(11):2421, 2004.
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138. Chanan-Khan AA, Miller KC, McCarthy P, Koryzna A, Kouides P, Donohue K, Mohr A, Bernstein ZP, Alam A, **Czuczman MS**. VAD-t (vincristine, adriamycin, dexamethasone and low-dose thalidomide) is an effective initial therapy with high response rates for patients with treatment naïve multiple myeloma (MM). *Blood* 104(11):3463, 2004.
139. Chanan-Khan AA, Miller Kena, Koryzna A, Takeshita K, McCarthy P, Mohr A, Donohue K, Bernstein ZP, Alam A, **Czuczman MS**. Thalidomide (T) in combination with fludarabine (F) as initial therapy for patients (pts) with treatment naïve chronic lymphocytic leukemia (CLL): Results of a Phase I trial. *Blood* 104(11):3476, 2004.
140. Hernandez FJ, Reddy N, Nallapareddy S, **Czuczman MS**. Biological effects of rabbit antithymocyte immunoglobulin (rATG, thymoglobulin @) in T-cell non-Hodgkin's lymphoma cell lines. *Blood* 104(11):4628, 2004.
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143. Chanan-Khan A, Miller KC, DiMiceli L, Padmanabhan S, Lawrence, Bernstein ZP, Takeshita K, Spaner D, Byrne C, Chrystal C, and **Czuczman MS**. Results of phase II study of Lenalidomide (L) {Revlimid<sup>®</sup>} in patients with relapsed or refractory chronic lymphocytic leukemia (CLL). *Blood* 106(11):447, 2005.
144. Younes A, Vose JM, Zelenetz AD, Smith MR, Burris H, Ansell S, Klein J, Kumm E, **Czuczman M**. Results of a Phase 2 trial of HGS-ETR1 (Agonistic Human Monoclonal Antibody to TRAIL Receptor 1) in subjects with relapsed/refractory non-Hodgkin's lymphoma (NHL). *Blood* 106(11):489, 2005.
145. Rodriguez MA, **Czuczman MS**, Friedberg JW, Koh ME, LaCasce AS, Millenson M, Auayport N, Niland J, Veer AT, Zelenetz AD, Weeks JC. Age significantly influences presentation and patterns of care in patients with newly diagnosed diffuse large cell lymphoma (DLCL): Collective data from 5 centers participating in the National Comprehensive Center Network (NCCN) NHL Outcomes Project. *Blood* 106(11):1335, 2005.
146. Hernandez-Ilizaliturri FJ, Devineni S, Arora S, Knight J, **Czuczman MS**. Targeting CD20 and Cd22 with rituximab in combination with CMC-544 results in improved anti-tumor activity against non-Hodgkin's lymphoma (NHL) pre-clinical models. *Blood* 106(11):1473, 2005.
147. Hernandez-Ilizaliturri FJ, Olejniczak SH, Knight J, **Czuczman MS**. Structural changes in the internal domain of CD20 antigen associated with the emergence of rituximab resistance: Effects of proteasome inhibition in CD20 structure and rituximab anti-tumor activity in rituximab-resistant cell lines (RRCL). *Blood* 106(11):1474, 2005.
148. **Czuczman MS**, Maddipati S, Knight J, Hernandez-Ilizaliturri FJ. In vitro synergistic anti-tumor activity by targeting death-receptor 4 (DR-4) and Cd20 antigen by combining HGS-ETR1 and rituximab monoclonal antibodies (mAbs) against non-Hodgkin's lymphoma cells (NHL). *Blood* 106(11):1475, 2005.
149. Friedberg JW, Leonard JP, Younes A, Fisher DC, Gordon LI, Moore JO, **Czuczman MS**, Miller TP, Stiff PJ, Cheson BD, Forero-Torres A, Finucane DM, Leigh BR, Molina A. Updated results from a phase II study of Galiximab (anti-CD80) in combination with rituximab for relapsed or refractory, follicular NHL. *Blood* 106(11):2435, 2005.
150. LaCasce A, Niland J, Kho ME, terVeer A, Friedberg JW, Rodriguez MA, **Czuczman MS**, Millenson M, Zelenetz AD, Nademanee AP, Weeks JC. Potential impact of pathologic review on therapy in non-Hodgkin's lymphoma (NHL): Analysis from the National Comprehensive Cancer Network (NCCN) NHL Outcomes Project. *Blood* 106(11):2816, 2005.
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152. Olejniczak SH, Hernandez-Ilizaliturri FJ, Clements JL, **Czuczman MS**. Lack of lipid raft domain reorganization following ligation of CD20 is associated with resistance to rituximab-induced complement-dependent cytotoxicity. *Blood* 106(11):4818, 2005.

153. Olejniczak SH, Hernandez-Ilizaliturri FJ, Clements JL, **Czuczman MS**. Loss of expression of the pro-apoptotic Bcl-2 family proteins Bak and Bax in rituximab- and chemotherapy-resistant non-Hodgkin's lymphoma cells. *Blood* 106(11):4819, 2005.
154. Hernandez-Ilizaliturri FJ, Kaur H, Bhinder A, Olejniczak S, Knight J, **Czuczman MS**. Impaired Ca<sup>++</sup> mobilization in rituximab-resistant cells (RRCL) is associated with changes in the structure of CD20 antigen, down-regulation of Bax/Bak pro-apoptotic proteins and up-regulation of the endoplasmic reticulum (ER) Ca<sup>++</sup> pump protein SERCA-3. *Proc ASCO* 24:2516, 2006.
155. Miller K, **Czuczman MS**, Dimiceli L, Padmanabhan S, Lawrence D, Bernstein Z, Takeshita K, Spaner D, Byrne C, Crystal C, Chanan-Khan AA. Lenalidomide (L) induces high response rates with molecular remission in patients (pts) with relapsed (rel) or refractory (ref) chronic lymphocytic leukemia (CLL). *Proc ASCO* 24:6517, 2006
156. Reddy NM, Hernandez-Ilizaliturri FJ, Olejniczak S, Knight J, **Czuczman MS**. Rituximab resistance and its association with changes in the internal domain of CD20 antigen and down-regulation of pro-apoptotic protein Bax and Bak in both rituximab-resistant cell lines (RRCL) and diffuse large B-cell lymphoma (DLBCL) patient (pt) samples. *Proc ASCO* 24:17509, 2006.
156. Block AW, Wallace PK, Miller KC, **Czuczman MS**, Chanan-Khan AA, Padmanabhan S. Correlation among poor prognostic indicators in B-cell chronic lymphocytic leukemia (B-CLL). *Am Soc of Human Genetics*. New Orleans, LA October 9-13, 2006.
157. Chanan-Khan AA, Miller KC, Musial L, Padmanabhan S, Lawrence D, Bernstein ZP, Takeshita K, Spaner D, Byrne C, Chrystal C, **Czuczman MS**. Clinical efficacy of lenalidomide (Revlimid) in patients with relapsed or refractory chronic lymphocytic leukemia (CLL): Updated results of a phase II clinical trial. *Blood* 108(11):306, 2006.
158. Chanan-Khan AA, Padmanabhan S, Miller KC, Musial L, Yu J, Bernstein ZP, Manochakian R, **Czuczman MS**. Final results of a phase II study of bortezomib (velcade) in combination with liposomal doxorubicin (Doxil) and thalidomide (VDT) demonstrate a sustained high response rates in patients (pts) with relapsed (rel) or refractory (ref) multiple myeloma. *Blood* 108(11):3539, 2006.

#### INVITED LECTURES / COURSES TAUGHT:

##### **Local / Regional (last 6 years):**

"Biotherapy of Cancer." SUNY at Buffalo School of Nursing graduate students. RPCI, Buffalo, NY January 31, 1994.

"Introduction to Hematology." D'Youville College, Physician Assistant Program, Buffalo, NY. April 18, 1994.

"Monoclonal Antibodies and Their Use in Clinical Medicine." SUNY at Buffalo/RPCI Nursing Continuing Education Program. RPCI, Buffalo, NY. October 14, 1994.

"Introduction to Hematology/Physiology of the Blood." D'Youville College, Physician Assistant Program, Buffalo, NY. April 6, 1995.

"Lymphoma" Millard Fillmore medical residents. Buffalo, NY. February 20, 1996.

"Current Treatment of GI Lymphomas" GI Grand Rounds, Buffalo General Hospital. Buffalo, NY. April 16, 1996.

"New Strategies in the Treatment of Low Grade Non-Hodgkin's Lymphoma." BGH Hematology/Oncology Grand Rounds. Buffalo, NY. November 12, 1996.

"Monoclonal Antibody Therapy of NHL". Oncology Grand Rounds. Strong Memorial Hospital. Rochester, NY. January 22, 1998.

"Monoclonal Antibody Therapy of NHL". Oncology Grand Rounds. SUNY at Syracuse. Syracuse, NY. January 22, 1998.

"Chimeric anti-CD20 monoclonal antibody therapy of low grade B-cell lymphoma". Regional Cancer Center Consortium for Biological Therapy of Cancer, Roswell Park Cancer Institute. Buffalo, NY. February 20, 1998.

An update on the use of monoclonal antibodies for the treatment of low grade non-Hodgkin's lymphoma. Community Physician Program. Buffalo, NY. February 24, 1998.

"Immunotherapy of non-Hodgkin's lymphoma: Recent advances". Summer Cancer Lecture Series, 1998. Chautauqua, NY. August 13, 1998.

"Immunotherapy of non-Hodgkin's lymphoma: Recent advances". Grand Rounds, Sisters of Charity Hospital, Buffalo, NY. September 8, 1998.

"Immunotherapy of non-Hodgkin's lymphoma: recent advances". The New York Cancer Society Symposium on Monoclonal Antibody Therapy for Lymphoma. New York, NY February 3, 1999.

"Update on Treatment of Relapsed NHL." Hematology/Oncology Grand Rounds. Memorial Sloan Kettering Cancer Center. New York, NY. June 22, 1999.

"Can Indolent B-cell Lymphoma be Cured? Integrating Monoclonal Antibodies into Current Treatment Strategies" Roswell Park Cancer Institute Medical Grand Rounds. Buffalo, NY February 25, 2000.

"Combination Chemotherapy and Rituximab." Monoclonal Antibodies in the Treatment of Lymphoma and Beyond. Satellite Symposium. New York, NY July 15, 2000.

"Monoclonal antibodies in B-cell lymphoma: Clinical applications." Pharmacy Oncology Symposium 2000. Buffalo, NY. October 27, 2000.

"Monoclonal Antibody Therapy of B-Cell Lymphoma: Review and Update". The Central New York Academy of Medicine's Dr. Lemuel Bowden Cancer Teaching Day. Utica, NY. May 17, 2001.

"Novel Strategies for the treatment of B cell lymphoma: Current status". Medicine Grand Rounds, SUNY Health Science Center. Syracuse, NY. August 15, 2002.

"Lymphoma Case Presentations". Hem/Onc Conference. SUNY Health Science Center. Syracuse, NY. August 15, 2002.

"NHL - Update and ASH 2002 Lymphoma Review". Century Medical Associates Oncology Tumor Board Meeting. Buffalo, NY. March 3, 2003.

"A Focus on Radioimmunotherapy – New Therapeutic Options in the Management of Non-Hodgkin's Lymphoma". Institute for Continuing Healthcare Education. Buffalo, NY. April 8, 2003.

"Follicular Lymphoma". NCCN Non-Hodgkin's Lymphoma Regional Guidelines Symposium. Buffalo, NY. November 13, 2003.

"Indolent Lymphoma: Review and Update". Advances in Hematologic Malignancies: A Comprehensive Review. Buffalo, NY. March 6, 2004.

"Meet the Expert on NHL". Leukemia & Lymphoma Society. Buffalo, NY. October 7, 2004

"Major Advances in the Treatment of B-cell Lymphoma". City Wide Grand Rounds, Buffalo, NY. January 20, 2005.

"Antibody Therapy for Lymphoma". Roswell Park Cancer Institute 2005 Trainee Lecture Series. Buffalo, NY. April 5, 2005.

"Meet the Expert on NHL". Leukemia & Lymphoma Society. Buffalo, NY. October 17, 2005.

#### **National (last 6 years):**

"ImmuRAIT -LL2 Lymphoma Therapy" (oral presentation). Society of Nuclear Medicine. New Vistas in Monoclonal Antibody Imaging and Therapy: Cancer and Infectious Diseases. Orlando, FL. June 4, 1994.

"Radioimmunotherapy of B-Cell Lymphomas with <sup>131</sup>I-Labeled LL2 Monoclonal Antibody" (oral presentation). Fifth Conference on Radioimmunodetection and Radioimmunotherapy of Cancer. Princeton, NJ. October 8, 1994.

"Chemoimmunotherapy of low-grade lymphoma with the anti-CD20 antibody IDEC-C2B8 in combination with CHOP chemotherapy" (oral presentation). Chemotherapy Foundation Symposium XIII: Innovative Cancer Therapy for Tomorrow. New York, NY. November 3, 1995.

"\*IDEC-C2B8/CHOP Chemoimmunotherapy in patients with low-grade lymphoma: clinical and bcl-2 (PCR) final results" (oral presentation). American Society of Hematology. Orlando, FL. December 9, 1996.

"Recent Advances in Monoclonal Antibody Therapy of Lymphoma" (oral presentation). Fourth International Congress on Biological Response Modifiers. San Antonio, TX. March 13, 1997.



"Will Unconjugated Monoclonal Antibody (mAb) Products be Approved as Cancer Treatment?" (oral presentation). Fourth International Congress on Biological Response Modifiers. San Antonio, TX. March 13, 1997.

"Is anti-CD20 plus chemotherapy more effective than chemotherapy in indolent lymphomas?" Lymphoma. . . The Next Questions. (oral presentation) New Orleans, LA. October 3, 1997.

"IDEC-C2B8 alone and in combination with CHOP in low grade B-cell lymphoma." Chemotherapy Foundation Symposium XV. (oral presentation) New York City, NY. November 12, 1997.

"Immunotherapy of low grade B-cell lymphoma with IDEC-C2B8". Grand Rounds, University of Pittsburgh. Pittsburgh, PA. February 5, 1998.

"Update on monoclonal antibody therapy of NHL". Grand Rounds, University of Arkansas, Little Rock, AR. February 12, 1998.

"Antibody Therapy of non-Hodgkin's Lymphoma." 16th Annual Conference: Clinical Hematology and Oncology. (oral presentation) San Diego, CA. February 18, 1998.

"Use of Monoclonal Antibodies in the Treatment of Lymphoid Malignancies." Lymphoid Malignancies in the New Millennium Symposium. (oral presentation) Morristown, NJ. September 9, 1998.

"Monoclonal antibodies for Lymphoma." Grand Rounds. The Rush Cancer Institute. Chicago, IL. October 30, 1998.

"Monoclonal antibodies for Lymphoma." Update in Leukemia and Lymphoma Annual Conference. Sponsored by the Cleveland Clinic Foundation. Cleveland, OH November 6, 1998.

"Rituxan monoclonal antibody therapy of B-cell lymphoma." Chemotherapy Foundation Symposium XVI. (oral presentation) New York City, NY. November 11, 1998.

"Monoclonal Antibodies: New therapeutic approaches in non-Hodgkin's lymphoma." Allogeneic Stem Cell Transplantation Conference. University of Nebraska Medical Center. Omaha, Nebraska. April 30, 1999.

"Rituxan in Combination Therapy of Low Grade B Cell Lymphoma". Chemotherapy Foundation Symposium XVII: Innovative Cancer Therapy for Tomorrow. New York, NY. November 3, 1999.

\*\*"Rituximab/CHOP chemoimmunotherapy in patients (pts) with low grade lymphoma (LG/F NHL): Progression free survival (PFS) after three years (median) follow-up." Selected for Poster Discussion Session, 1999 American Society of Hematology Meeting, New Orleans, LA, December, 1999.

"Monoclonal Antibody Therapy in Non-Hodgkin's Lymphoma." Medical Grand Rounds, University of Maryland Greenbaum Cancer Center, Baltimore, MD February 7, 2000.

"Combination of Rituxan and CHOP in Patients with Low Grade Lymphoma (LG/F NHL): Progression-free Survival after Three Years (median) Follow-up. International Conference on Advances in Cancer Immunotherapy. Princeton, NJ March 2, 2000.

"New modalities of therapy for non-Hodgkin's lymphoma". Grand Rounds, Mercy Hospital. Pittsburgh, PA. April 13, 2000.

"Advances in monoclonal antibody therapy for non-Hodgkin's lymphoma". Hematology Grand Rounds. University of Southern California. Los Angeles, CA. May 5, 2000.

"Integrating mAbs into therapy for non-Hodgkin's lymphoma". Integrating monoclonal antibody therapy into cancer therapy strategies: Recent insights and prospects for Oncology in the 21<sup>st</sup> Century. American Society of Clinical Oncology 36<sup>th</sup> Annual Meeting. New Orleans, LA. May 19, 2000.

"Rituximab Immunotherapy: Review and Update" Chemotherapy Foundation Symposium XVIII, Innovative Cancer Therapy for Tomorrow. New York City, NY November 8, 2000.

"Rituximab in Combination with CHOP or Fludarabine in Low-Grade Lymphoma" Recent Advances and Future Directions with Rituxan (Rituximab). Kona, HI. January 12, 2001.

"Diffuse Large B-Cell Lymphoma – Choice of Therapy" Challenging Cases in Hematology by Network for Oncology Communication and Research. Atlanta, GA., April 20, 2001.

"Follicular Lymphoma – 1<sup>st</sup> Relapse" Challenging Cases in Hematology by Network for Oncology Communication and Research. Atlanta, GA., April 20, 2001.

"Update and Review of Monoclonal Antibodies in B Cell Malignancies". The University of Chicago, Visiting Professor in Oncology. Chicago, IL., June 18, 2001.

"Innovative Therapy of Non-Hodgkin's Lymphoma." Cancer Center Grand Rounds. Karmanos Cancer Institute. Detroit, MI. September 27, 2001.

"Update and Review of Monoclonal Antibodies in B-Cell Malignancies." 7<sup>th</sup> Annual Jaffar Oncology Conference. Strategies for a Cure: Innovations in Cancer Treatment for the 21<sup>st</sup> Century. Dearborn, MI. September 28, 2001.

"Radioimmunotherapy for Lymphoma." 2002 Joint Cancer Conference of the Florida Universities. Orlando, FL. February 1, 2002.

"Lymphoma – Low Grade", ASH Highlights #3. New Orleans, LA. March 2, 2002.

"Indolent Lymphoma – Front-Line and First-Relapse". The Visiting Faculty Program on B-Cell Hematologic Malignancies and Disorders: Case Study Development/Review Meeting. American Society of Clinical Oncology. Orlando, FL. May 16, 2002.

"New Strategies for the Treatment of Low-Grade Lymphoma: Current Status". Indolent Lymphoid Malignancies: New Challenges and Therapeutic Advances. American Society of Clinical Oncology. Orlando, FL. May 17, 2002.

“Monoclonal Antibodies in Combination with Chemotherapy for the Treatment of Non-Hodgkin’s Lymphoma”. Institute for Continuing Healthcare Education. New York, NY. June 11, 2002.

“Monoclonal Antibody Therapy: Review and Update”. Grand Rounds, St. Luke’s-Roosevelt Hospital Center. New York, NY. June 12, 2002.

“Expanding options in the treatment of non-Hodgkin’s lymphoma”. The Regional Cancer Center. Erie, PA. September 26, 2002.

“Lymphoma: State of the art”. International Oncology Network Meeting. Newark, NJ. October 10, 2002.

“New initiatives in low grade lymphoma”. CALGB Fall Group Meeting. Tampa, FL. November 8, 2002.

“ASH 2002 Updates: Low-grade non-Hodgkin’s lymphoma.” Third Annual Rush Review. Chicago, IL. February 22, 2003.

“Indolent Non-Hodgkin’s Lymphoma”. A Comprehensive Board Review in Hematology and Medical Oncology. Dallas, TX. October 9, 2003.

“Diffuse Large B-cell Lymphoma – Initial Therapy”. Network for Oncology Communication and Research Roadmap to Follicular Lymphoma – Challenging Cases in Hematology. New York, NY. November 15, 2003.

“Indolent Lymphoma”. International Oncology Network ASH Review. Orlando, FL. January 23, 2004.

“Update: Non-Hodgkin’s Lymphoma”. National Comprehensive Cancer Network’s 9<sup>th</sup> Annual Conference: Clinical Practice Guidelines and Outcomes Data in Oncology. Hollywood, FL. March 13, 2004.

“Rituximab Translational Research Studies: Making a Good Thing Better!” Joint Lymphoma and Bone Marrow Transplantation Translational Research Seminar. Dallas, TX. May 26, 2004.

“Diffuse Large B-cell Lymphoma”. Network for Oncology Communication and Research: Challenging Cases in Hematology. Chicago, IL. September 18, 2004.

“New Therapeutic Options in the Management of Non-Hodgkin’s Lymphoma” Advances in the Treatment of Non-Hodgkin’s Lymphoma: A Focus on Radioimmunotherapy. Ford City, PA. September 20, 2004.

“Indolent Non-Hodgkin’s Lymphomas”. Comprehensive Board Review in Hematology and Medical Oncology. MD Anderson Cancer Center. October 2, 2004.

“Treatment Options for Patients with Low Grade Non-Hodgkin’s Lymphoma”. 2<sup>nd</sup> Annual Symposium on Hematologic Malignancies. Charleston, SC. October 3, 2004.

“Lymphoma Overview”. Christiana Care Health Services, Helen F. Graham Cancer Center, Delaware Community Clinical Oncology Program Summit. Wilmington, DE. October 14, 2004.

"Mantle Cell Lymphoma". Network for Oncology Communication and Research, Challenging Cases in Hematology. New York, NY. October 16, 2004.

"Indolent Lymphoma and RIT". International Oncology Network, ASH Review. Orlando, FL. January 15, 2005.

"Low-grade Non-Hodgkin's Lymphoma". 5<sup>th</sup> Annual RUSH Review. Chicago, IL. January 29, 2005.

"Sunday Brunch with the Experts: Non-Hodgkin's Lymphoma". National Comprehensive Cancer Network's 10<sup>th</sup> Annual Conference. Hollywood, FL. March 20, 2005.

"Innovations in the Treatment of Indolent and Aggressive Lymphomas". The 1112<sup>th</sup> Cancer Seminar of The Southern California Academy of Clinical Oncology (SCACO). Century City, CA. June 8, 2005.

"Follicular Lymphoma: Advanced Disease". 2005 Pan Pacific Lymphoma Conference. Kauai, Hawaii. July 13, 2005.

"Transformed Lymphoma". 2005 Pan Pacific Lymphoma Conference. Kauai, Hawaii. July 13, 2005.

"Update and review of CALGB 50402: Extended induction therapy of galiximab plus rituximab in previous untreated follicular lymphoma patients." GALGB Fall Meeting. Amelia Island Plantation, FL. November 18, 2005.

#### **International (last 6 years):**

"IDEC-C2B8/CHOP chemoimmunotherapy in patients with low grade lymphoma: Interim clinical and bcl-2 (pcr) results." Poster presentation at the 9th NCI-EORTC Symposium on New Drugs in Cancer Therapy. Amsterdam, Netherlands. March 13, 1996.

"The anti-CD20 antibody IDEC-C2B8 clears lymphoma cells bearing the t(14;18) translocation (bcl-2) from the peripheral blood and bone marrow of a proportion of patients with low-grade or follicular non-Hodgkin's lymphoma" (poster presentation at European Society of Medical Oncology annual meeting). Vienna, Austria. November 3, 1996.

"U.S. Experience with IDEC-C2B8 monoclonal antibody and future trials." European Lymphoma Advisory Panel. Lisbon, Portugal. January 11-15, 1997.

"Update on CALGB 8364: Immunophenotyping of Adult ALL". CALGB Spring Meeting. Montreal, Quebec. June 20-22, 1997.

"IDEC-C2B8/CHOP chemoimmunotherapy in patients with low grade lymphoma: Clinical and bcl-2 (PCR) results." Satellite symposium to XIX symposium of the International Association for Comparative Research on Leukemia and Related Disorders. Mannheim, Germany. July 13, 1997.

"New approaches in the treatment of lymphoma: U.S. experience with IDEC-C2B8 (Rituximab) in the treatment of indolent lymphoma." Brazilian Congress. Sao Paulo, Brazil. August 14-18, 1997.

"U.S. experience with the CD20 antibody, Rituximab, as single agent treatment in indolent lymphoma." International Society of Experimental Hematology Meeting. Cannes, France. August 24-29, 1997.

"Rituximab as combination therapy - the US experience." Innovative antibody therapies for lymphoma. Hamburg, Germany. September 14, 1997.

"Clinical results of anti-CD20 MAB in combination with CHOP in relapsed B-cell Lymphoma." Annual Joint Meeting of the German and Austrian Societies for Hematology and Oncology. Linz, Austria. October 14, 1997.

"Modern Therapies for Low Grade Lymphoma". National Meeting of Heads of Hematology / Oncology Centers in Poland. Warsaw, Poland. March 13, 1998.

"The Role of MabThera in Indolent NHL". IX Congress of the International Society of Hematology, Asian-Pacific Division. Bangkok, Thailand. October 24-28, 1999.

"Combination chemotherapy and MabThera". European Hematology Association-5 Congress, Birmingham, England. June 25-28, 2000.

"Treatment of low-grade and aggressive B-cell lymphoma with the combination of chemotherapy plus Rituximab". German and Austrian Society of Hematology and Oncology (DOGH). Graz, Austria. October 22-24, 2000.

"Overview of chemoimmunotherapy of NHL" German and Austrian Society of Hematology and Oncology (DOGH). Graz, Austria. October 22-24, 2000.

"Immunotherapy of Indolent NHL" European Hematology Association-6 Congress. Frankfurt, Germany. June 21, 2001.

"Zevalin™ Radioimmunotherapy (RIT) of Rituxan-Refractory Follicular non-Hodgkin's Lymphoma" European Hematology Association-6 Congress. Frankfurt, Germany. June 23, 2001.

"Indolent Lymphoma Debate: Conservative or Aggressive Management?" MabThera Present and Future Time to Re-assess. Montreux, Switzerland. October 6, 2001.

"Updated Results from the Pivotal Study." MabThera Present and Future Time to Re-assess. Montreux, Switzerland. October 6, 2001.

"Rituximab (MabThera™) Combination Immunotherapy in B-Cell Lymphoma" 43<sup>rd</sup> Annual Meeting of the Japanese Society of Clinical Oncology. Kobe, Japan. November 13, 2001.

"Rituximab (MabThera™) Monotherapy of B-Cell Lymphoma" 43<sup>rd</sup> Annual Meeting of the Japanese Society of Clinical Oncology. Kobe, Japan. November 13, 2001.

"Treatment of Low and Intermediate/High Grade B-cell Lymphoma with the Combination of Chemotherapy plus Rituximab." New Therapy Strategies of Non-Hodgkin's Lymphoma, German Cancer Congress. Berlin, Germany. March 11, 2002.

"Results of Retreatment with MabThera for Patients with Non-Hodgkin's Lymphoma." New Therapy Strategies of Non-Hodgkin's Lymphoma, German Cancer Congress. Berlin, Germany. March 11, 2002.

"Update on the use of MabThera in mantle cell lymphoma." MabThera Scientific Meeting, MabThera: Realising Therapeutic Potential. Noosa, Australia. February 7, 2003.

"Use of MabThera in combination immunotherapy for indolent lymphomas." MabThera Scientific Meeting, MabThera: Realising Therapeutic Potential. Noosa, Australia. February 8, 2003.

"Rituximab in Low-Grade and Mantle-Cell NHL: Review and Update". Annual Meeting of the Quebec Association of Hematologists and Oncologists. Quebec, Canada. March 29, 2003.

"Treatment of the Indolent NHL Patient". 2003 Eastern Canadian Oncology Summit. Muskoka, Ontario. September 7, 2003.

"MabThera plus CHOP or Fludarabine: An Update on Two Phase II Trials". Evolution and Revolution in NHL Therapy. Monte Carlo. November 1, 2003.

"Indolent Lymphoma: Past, Present and Future". Grand Rounds, Kitchener Cancer Center. Kitchener, Ontario. May 13, 2004.

"Indolent B-cell Lymphoma: Past, Present, and Future". Lymphoma Tumor Group, Vancouver Centre of the British Columbia Cancer Agency. June 25, 2004.

"Case Studies in the Treatment of Indolent B-cell Lymphoma: What would you do?". Lymphoma Tumor Group, Vancouver Centre of the British Columbia Cancer Agency. June 25, 2004.

"Human Polyclonal Antibodies" 3<sup>rd</sup> International Workshop on Non-Hodgkin's Lymphoma. Stresa, Italy. August 29, 2004.

"Rituximab-Containing Immunochemotherapy of B-Cell Lymphoma" The 67<sup>th</sup> Annual Meeting of the Japanese Society of Hematology (JSH) and the 4<sup>th</sup> Annual Meeting of the Japanese Society of Clinical Hematology (JSCHE). Tokyo, Japan. September 17, 2005.

"Monoclonal Antibodies - CD80, Galiximab" Meeting New Drugs in Hematology, Bologna, Italy. October 10, 2005.

"New developments in the treatment of lymphoma." Ontario Canada Cancer Centers (London, Windsor, Cambridge, and St. Catharines). November, 2005.

